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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/825,618	04/03/2001	Roberto Ciaff	FHW-076	3283
959	7590	01/28/2004		
LAHIVE & COCKFIELD, LLP. 28 STATE STREET BOSTON, MA 02109			EXAMINER BRADFORD, RODERICK D	
			ART UNIT	PAPER NUMBER
			3762	//

DATE MAILED: 01/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/825,618

Applicant(s)

CIAFF, ROBERTO

Examiner

Roderick Bradford

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 1,2 and 4-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3 and 25-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Claims 1, 2 and 4-24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 10.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Palermo et al. U.S. Patent No. 5,562,718 in view of Cheney U.S. Patent No. 1,557,417.

Referring to claim 1, Palermo discloses a control module for controlling the parameters of an electrical pulse suitable for innervating nerves and tissue (10), and one or more conductor tools for delivering the electrical pulse to the nerves (Fig. 1), wherein the control module is configured to enable the adjustment of the width of the electrical pulse at levels in the range 1/30000 (33 μ s) to 1/7500 (132 μ s) (Figs. 4a and 4b) and pulse repetition frequency at levels below 500 Hz (500IMP/s) (column 10, lines 29-30) and a peak output voltage of the of the pulse in the range 0 to 130V (column 10, lines 12-20). Cheney discloses at least one conductor tool comprising a frame of electrically conductive roller and a handle of electrically insulating material, the roller

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being mounted in electrically conductive communication with the frame, and means for electrically connecting the tool with a controlled electrical pulse (Fig. 1).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the teachings of Palermo to include at least one conductor tool comprising a frame of electrically conductive roller and a handle of electrically insulating material, the roller being mounted in electrically conductive communication with the frame, and means for electrically connecting the tool with a controlled electrical pulse, as taught by Cheney, as an alternate means of stimulation.

Referring to claim 25, Palermo in view of Cheney discloses the claimed invention except for wherein the range of pulse width levels includes $1/15000$ ($66\mu\text{s}$). It would have been an obvious matter of design choice to one skilled in the art to modify the teachings of Palermo in view of Cheney to have the range of pulse width levels which includes $1/15000$ ($66\mu\text{s}$), since applicant has not disclosed that the range of pulse width levels which includes $1/15000$ ($66\mu\text{s}$) provides any criticality and/or unexpected results and it appears that the invention would perform equally well with any pulse width levels, such as the pulse width levels as taught by Palermo in view of Cheney, as a means of providing more efficient stimulation.

Referring to claim 27, Palermo discloses wherein the controlled parameters include the polarity of the electrical pulse (column 11, lines 57-67).

Referring to claim 28, Palermo discloses wherein the conductor tools include electrode pads (Fig. 1).

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Referring to claim 26, Palermo discloses wherein the pulse repetition frequency is controllable in a range of 1 Hz and 115 Hz (column 10, lines 29-30).

Referring to claim 29, Palermo in view of Cheney discloses the claimed invention except for wherein the conductor tools include electrode pads having an active area of about 60 mm by about 45 mm. It would have been an obvious matter of design choice to one having ordinary skill in the art to modify the device of Palermo in view of Cheney to include wherein the conductor tools include electrode pads having an active area of about 60 mm by about 45 mm, since applicant has not disclosed that a conductor tool that includes electrode pads having an active area of about 60 mm by about 45 mm provides any criticality and/or unexpected results and it appears that the invention would perform equally well with any size electrode pads, such as the electrode pads as taught by Palermo in view of Cheney, as a means to provide stimulation.

4. Claims 30 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Palermo et al. U.S. Patent No. 5,562,718 in view of Cheney U.S. Patent No. 1,557,417 as applied to claim 3 above, and further in view of Miller et al. U.S. Patent No. 4,846,181.

Referring to claim 30, Palermo in view of Cheney disclose the claimed invention except for further comprising a bath suitable for receiving and holding saline solution at a temperature of between about 36°C and 42°C. However, Miller discloses a bath suitable for receiving and holding saline solution (Fig. 2) at a temperature of between about 36°C and 42°C (column 13, lines 50-65) as an alternate means to promote tissue healing.

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It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the teachings of Palermo in view of Cheney, to include a bath suitable for receiving and holding saline solution at a temperature of between about 36°C and 42°C, as taught by Miller, as an alternate means to promote tissue healing.

Referring to claim 31, Palermo in view of Cheney and in further view of Miller discloses the claimed invention except for wherein the bath comprises a control panel for monitoring/or controlling inter alia the temperature of fluid contained therein. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device as taught by Palermo in view of Cheney and in further view of Miller, with a control panel for monitoring/or controlling the temperature of a fluid since it was well known in the art to have a control panel for monitoring/or controlling the temperature as a means ensuring the solution is not too cold or hot for the patient.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roderick Bradford whose telephone number is (703) 305-3287. The examiner can normally be reached on Monday - Friday 7 a.m. - 4 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9302.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Angela D. Sykes

R. B.
R.B.

ANGELA D. SYKES
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